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EXAMINER

TRAN, MY CHAU T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1639

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/549,970

Applicant(s)

RAVKIN ET AL.

Examiner

My-Chau T. Tran

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003 and 01 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-41, 45 and 54-68 is/are pending in the application.
- 4a) Of the above claim(s) ³¹~~30~~, 38-40, 54-59, 60-62, and 66-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) ^{30 32}~~26-29, 31~~ 30-37, 41, 45, 63-65, and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13. 6) ☐ Other: _____

Art Unit: 1639

DETAILED ACTION

Note: The examiner for your application in the PTO has changed. However, the Group and/or Art Unit location of your application in the PTO remained the same, which is Group Art Unit 1639.

1. Applicant's amendment filed 2/3/03 in Paper No. 15 is acknowledged and entered. Claims 42-44 are canceled by the amendment. Claims 26-27, 29-31, 34-36, and 40 are amended by the amendment. Claims 54-59 are added by the amendment.
2. Applicant's amendment filed 5/1/03 in Paper No. 17 is acknowledged and entered. Claim 26 is amended by the amendment. Claims 60-68 are added by the amendment.
3. Claims 26-41, 45, and 54-68 are pending.

Election/Restrictions

4. Applicant's species election **without** traverse in Paper No. 8 is acknowledged and entered. The elected species are follows:
 - a) Species of surface: glass. (read on Claim 32).
 - b) Species of coded carriers: chips. (read on Claim 30).
 - c) Species of how (the manner in which) carriers are coded: color coded. (read on Claims 28-29 and Claim 41).
 - d) Species of different chemical compounds: nucleic acids. (read on Claim 37).

Art Unit: 1639

5. Claims 31, and 38-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected species**, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8. *(Note: Claim 30 is not withdrawn from consideration as stated in the previous Office Action (i.e. Paper No. 12). Claim 31 was examined in the previous Office Action have been withdrawn since “nanocrystal” would not read on the elected carriers that is “chips”).*

6. The newly added Claims 54 and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a **nonelected species**, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

7. Claims 26-30, 32-37, 41, 45, 55-61, and 63-68 are treated on the merit in this Office Action.

Withdrawn Rejections

8. The previous objection for claim 36 has been withdrawn in view of applicant's amendments of claim 36.

9. The previous rejection 35 USC 112, first paragraph, for claim 26 has been withdrawn in view of applicant's amendments of claim 26 filed on 2/3/03.

10. The previous rejection 35 USC 112, first paragraph, for claims 42-44 has been withdrawn in view of applicant's cancellation of claims 42-44 filed on 2/3/03.

Art Unit: 1639

11. The previous rejections 35 USC 112, second paragraph, for claims 26-29, 31-37, and 41-45 have been withdrawn in view of applicant's amendments of claims 26-27, 29-31, 34-36, and 40 filed on 2/3/03, cancellation of claims 42-44 filed on 2/3/03, and argument.

12. **Claim 31** was inadvertently examine in the previous Office Action, which is drawn to a non-elected species that is "nanocrystal". And, the previous rejections under 35 USC 102(e) as being anticipated by Castro et al. (US Patent 6,114,038) for claims 26-28, 31, 32, 35, 37, and 41-44 have been withdrawn in view of applicant's argument that 'nanocrystals would not be considered a "carrier" (see pg. 11 of response filed 2/3/03, line 8).

Maintained Rejections

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

14. Claims 26-29, 32, and 41-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Nova et al. US Patent No. 5,741,462 April 1998.

The Nova et al. reference discloses remotely programmable matrices for use in immunological, analytical, chemical, and biological assays (abstract). Column 4, lines 52-61, discloses that the matrices may be glass or a polymer, for example, and may be in the form of a continuous surface (as a glass tube or microtiter plate) or particulates. Column 5, lines 10-35, discloses a data storage device with encoded information that identifies molecules or biological particles that are in close proximity with the matrix and that the device may include a support matrix disposed on an outer surface of a shell for retaining molecules or biological particles (i.e.

Art Unit: 1639

the molecules or biological particles may be attached to the recording devices). Column 6, lines 1-4, discloses that the recording devices may be placed in or on the matrix. Column 11, lines 7-38, discloses that the encoding device may include an electromagnetic tag (including visible light). Column 19, lines 1-12, discloses that the recording devices may be optically programmable read/write devices. Column 25, lines 48-65, discloses an optical encoding system that uses different wavelengths (colors) of light. Column 30, lines 18-23, discloses an array of memories (devices) embedded in a matrix (i.e. arbitrarily distributed on a surface) with different antibodies linked to different memories. Accordingly, the Nova et al. reference anticipates present claims 26-28, 32, and 41-44.

Column 25, lines 53-59, discloses that multiple spectral holes can be superimposed on a programmable information device (i.e. multiple wavelengths of light may pass through), anticipating present claim 29. Column 26, lines 1-23, discloses the use of optical disks, which require a flattened tube and at least on flat surface for alignment with an optical writing device, anticipating present claim 45.

Response to Arguments

15. Applicant's argument(s) filed 2/3/03 in Paper No. 15 directed to the above rejection was considered but they are not persuasive for the following reasons.

Applicant contends that “[N]ova neither teaches nor suggest any type of system that acquires an image of a heterogeneous mixture of coded carriers distributed on a surface in combination with an analysis system that uses code information from the image to interpret experiments” (see response pg. 10, lines 4-6).

Applicant's arguments are not convincing since Nova et al. do suggest a 'system that acquires an image of a heterogeneous mixture of coded carriers distributed on a surface in combination with an analysis system that uses code information from the image to interpret experiments'. Nova et al. disclose an optically programmed device that "[T]he recording medium is photochemically active so that exposure to laser light of the appropriate wavelength will form spectral holes. Because different wavelengths are used, multiple spectral holes can be superimposed so that the recording medium can be very small for purposes of tagging. Further, since only a single bit of information is required to tag the particle at any given step, the creation of a single spectral hole at a specific wavelength is capable of providing all of the information needed. The host computer then makes a record associating the process performed with a particular laser wavelength." Therefore, the Nova et al. reference anticipates present claims 26-28, 32, and 41-44 as amended in Paper No. 15.

Claim Rejections - 35 USC § 103

16. Claims 26-29, 32-37, and 41-45 rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al. US Patent No. 5,741,462 April 1998.

The Nova et al. reference discloses remotely programmable matrices for use in immunological, analytical, chemical, and biological assays (abstract). The matrix material may be glass or a polymer, for example, and may be in the form of a continuous surface (as a glass tube or microtiter plate) or particulates. The reference teaches a data storage device with encoded information that identifies molecules or biological particles that are in close proximity with the matrix and that the device may include a support matrix disposed on an outer surface of

Art Unit: 1639

a shell for retaining molecules or biological particles (i.e. the molecules or biological particles may be attached to the recording devices). The recording devices may be placed in or on the matrix and the encoding device may include an electromagnetic tag (including visible light). The recording devices may be optically programmable read/write devices that use different wavelengths (colors) of light. Multiple spectral holes can be superimposed on a programmable information device. Column 30, lines 18-23, teaches an array of memories (devices) embedded in a matrix (i.e. arbitrarily distributed on a surface) with different antibodies linked to different memories.

The Nova et al. reference does not specifically teach using a CCD camera or acquiring digital images, the use of a microscope or confocal optics. It would have been obvious to one of ordinary skill in the art at the time that the invention was made to select from a variety of optical reading devices such as a CCD camera for obtaining digital images or a microscope with confocal optics. One would have been motivated to do so because digital cameras would produce digital images for computer processing and confocal microscopes would be useful for enlarging images of small assay areas. One would have had a reasonable expectation for success because digital image capture and the use of confocal microscopes was routine in the art.

Response to Arguments

17. Applicant's argument(s) filed 2/3/03 in Paper No. 15 directed to the above rejection was considered but they are not persuasive for the following reasons.

Applicant alleges that “[N]ova neither teaches nor suggest any type of system that acquires an image of a heterogeneous mixture of coded carriers distributed on a surface and then

Art Unit: 1639

uses code information from the image to interpret experiments on analytes carried by the carrier”
(see response pg. 11, lines 17-19).

Applicant’s arguments are not convincing since Nova et al. do suggest a ‘system that acquires an image of a heterogeneous mixture of coded carriers distributed on a surface in combination with an analysis system that uses code information from the image to interpret experiments’ as discussed above for the rejection under 35 U.S.C. 102(e) as being anticipated by Nova et al. US Patent No. 5,741,462 April 1998.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 26-30, 32-37, 41, 45, 55-61, and 63-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claims 26 and 68 recite ‘*a mixture of at least two carriers randomly distributed on the surface*’.

The instant claim 55 recites ‘*a mixture of at least two carriers disposed on the surface*’.

The instant claim 66 recites ‘*a mixture of at least two flat carriers randomly distributed on the surface*’.

The recitation of 'a mixture of at least two carriers randomly distributed on the surface', 'a mixture of at least two carriers disposed on the surface', and 'a mixture of at least two flat carriers randomly distributed on the surface' claimed in claim, have no clear support in the specification and the claims as originally filed. The specification disclosed "the composition is formed by a mixture of carriers from different reaction vessels" (pg. 8, line 20-21) is not support for 'a mixture of at least two carriers randomly distributed on the surface', 'a mixture of at least two carriers disposed on the surface', and 'a mixture of at least two flat carriers randomly distributed on the surface'. Because the narrow limitation of the specification recites '[T]he composition is formed by a mixture of carriers from different reaction vessels' (e.g. the "mixture" is a "mixture" of composition in a reaction vessels), does not support the broad limitation of the claims, which recite 'a mixture of at least two carriers randomly distributed on the surface', 'a mixture of at least two carriers disposed on the surface', and 'a mixture of at least two flat carriers randomly distributed on the surface'. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of 'a mixture of at least two carriers randomly distributed on the surface', 'a mixture of at least two carriers disposed on the surface', and 'a mixture of at least two flat carriers randomly distributed on the surface'.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

20. Claims 26-30, 32-37, 41, 45, 60-61, and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

Art Unit: 1639

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claim 26 recites *'by producing a mask for each carrier or set of carrier having the same code, and measuring one or more reporting modalities within each mask'*.

The recitation of *'by producing a mask for each carrier or set of carrier having the same code, and measuring one or more reporting modalities within each mask'* claimed in claim, have no clear support in the specification and the claims as originally filed. The specification in page 17 as indicated by applicant disclosed 'these probes can be attached to the carriers by a biotin-avidin linkage or other chemical linkage of appropriate length that keeps the beacon molecule from physically interacting with the surface of carrier' (lines 18-20); in page 21 as indicated by applicant disclosed 'if carriers are different by color, a set of images, corresponding to different spectral bands, may be acquired. A combination of these images can be used to produce and analyze the mask of the beads as described in the previous paragraphs. For each bead mask relative image values can be determined in all spectral images. Each bead color will generate a characteristic set of these values, which can be used to identify them' (lines 12-17); and figure 12 is not support for *'by producing a mask for each carrier or set of carrier having the same code, and measuring one or more reporting modalities within each mask'*. Because the narrow limitation of the specification recites on page 17, page 21, and figure 12 as indicated by applicant (e.g. probes that can be attached to the carrier and mask of beads), does not support the broad limitation of the claim, which recites *'by producing a mask for each carrier or set of carrier having the same code, and measuring one or more reporting modalities within each mask'*. Therefore, the scope of the invention as originally disclosed in the specification would not

Art Unit: 1639

encompass the scope of the limitation of *'by producing a mask for each carrier or set of carrier having the same code, and measuring one or more reporting modalities within each mask'*.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "thresholded" of claim 65 is a relative term, which renders the claim indefinite. The term "thresholded" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 26-30, 32-37, 41, 45, 55-61, and 63-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung et al. (US Patent 5,143,854).

Pirrung et al. disclose a device wherein the polymers array (carriers) is synthesized on a substrate (Abstract). The surface of the substrate comprise of the same material as the substrate such as inorganic glasses (col. 11, lines 51-57) (refers to “(a)” of Claims 26, 55, 66, and 68; Claim 32). A single substrate supports comprise of more than about 10 different monomer sequences (i.e. polymer arrays) (refers to a mixture of at least two carriers). The polymer arrays are randomly distributed on the surface (fig. 10M; col. 24, lines 45-47). The polymer arrays can bind to a receptor (refers to carriers carrying an analyte), which have an affinity to a specific ligand such as DNA (refers to claim 37) (Abstract; col. 6, lines 41-68 to col. 7, lines 1-20). The polymer arrays comprise of any shape or size (col. 15, lines 49-51) (refers to “flat carriers”). The polymer arrays are labeled (col. 4, lines 12-16) (refers to optically detectable code). The substrate is placed in a microscope detection apparatus (refers to an image device and Claim 35) for identification of locations where binding takes place (col. 4, lines 14-27) (refers to an image systems and Claim 33). Therefore, the device of Pirrung et al. anticipates that of the presently claimed invention.

The instant claims 64-65 (e.g. the digital image is corrected for background variation (claim 64) and the digital image is thresholded (Claim 65)) are written as product-by-process claims. *“Eventhough the product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claims is same or as obvious from the product of the prior art, the claim is unpatentable eventhough the prior art product was made by a different process.”* In re Thorpe, 777 F. 2d 695, 698, 227 U. S. P. Q. 964, 966 (Fed. Cir. 1985). (See MPEP 2113).

25. Claims 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US Patent 4,053,433).

Lee discloses a device wherein color-coded microparticle 'consists of microscopic pieces of colored plastic films fused (refers to flat carriers) together to form a rectangular "microsandwich". The microsandwich is a generally rectangular hexahedron, which has ten color segments in sequence, with no segments of the same color being adjacent to one another. The code may be read from left to right or right to left (refers to image analysis system)' (col. 4, lines 49-63; fig. 4). The identification of the microparticles is by means of 'visual inspection of a single microparticle with a microscope or other magnifying means' (Abstract; col. 2, lines 14-17) (refers to imaging device). Therefore, the device of Lee anticipates the presently claimed invention.

Conclusion

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1639

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
June 27, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER